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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,005	02/17/2005	Miguel Mulet Parada	2005_0260A	1908

513 7590 10/30/2007

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EXAMINER	
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ART UNIT	PAPER NUMBER
2624	

MAIL DATE	DELIVERY MODE
10/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)
	10/525,005	MULET PARADA ET AL.
	Examiner	Art Unit
	Nathan Bloom	2624

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-23* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 20-23* is/are rejected.

7)☒ Claim(s) *19* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *02/17/2005,12/28/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statement filed 12/28/2005 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because the reference is not a legible copy. It has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Objections

1. Claim is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The USPTO "Interim Guidelines for Examination of Patent Applications for Patent Subject Matter Eligibility" (Official Gazette notice of 22 November 2005), Annex IV, reads as follows:

Descriptive material can be characterized as either "functional descriptive material" or "nonfunctional descriptive material." In this context, "functional descriptive material" consists of data structures and computer programs which impart functionality when employed as a computer component. (The definition of "data structure" is "a physical or logical relationship among data elements, designed to support specific data manipulation functions." The New IEEE Standard Dictionary of Electrical and Electronics Terms 308 (5th ed. 1993).) "Nonfunctional descriptive material" includes but is not limited to music, literary works and a compilation or mere arrangement of data.

When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized. Compare In re Lowry, 32 F.3d 1579, 1583-84, 32 USPQ2d 1031, 1035 (Fed. Cir. 1994) (claim to data structure stored on a computer readable medium that increases computer efficiency held statutory) and Warmerdam, 33 F.3d at 1360-61, 31 USPQ2d at 1759 (claim to computer having a specific data structure stored in memory held statutory product-by-process claim) with Warmerdam, 33 F.3d at 1361, 31 USPQ2d at 1760 (claim to a data structure per se held nonstatutory).

In contrast, a claimed computer-readable medium encoded with a computer program is a computer element which defines structural and functional interrelationships between the computer program and the rest of the computer which permit the computer program's functionality to be realized, and is thus statutory. See Lowry, 32 F.3d at 1583-84, 32 USPQ2d at 1035.

Claim(s) 20-21 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter as follows. Claims 20-21 define a "computer program comprising program code" and a "computer program product" embodying functional descriptive material. However, the claim does not define a computer-readable medium or memory and is thus non-statutory for that reason (i.e., "When functional descriptive material is recorded on some computer-readable medium it becomes structurally and functionally interrelated to the medium and will be statutory in most cases since use of technology permits the function of the descriptive material to be realized" – Guidelines Annex IV). That is, the scope of the presently claimed "computer program" and "computer program product" can range from paper on which the program is written, to a program simply contemplated and memorized by a person. The examiner suggests amending the claim to embody the program on "computer-readable medium"

or equivalent in order to make the claim statutory. Any amendment to the claim should be commensurate with its corresponding disclosure.

Examiner notes that a "computer-readable medium" is neither defined nor supported by the Applicants' disclosure.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 1-9, and 15-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ladak (US 2004/0218797) and Lobregt ("A Discrete Dynamic Contour Model") in view of Cootes ("Statistical Models of Appearance for Medical Image Analysis and Computer Vision")

Instant claim 1: A method of computing a contour comprising the steps of:

inputting a plurality of points, each point being indicative of a predetermined landmark point in an image; [*Ladak describes a plurality of inputted points in paragraphs 0028, 0046-0048, and Figures 1, 8-11, and 13.*]

deriving a preliminary contour based on the input points and a known average contour shape; [*Ladak in paragraph 0028 teaches creating a preliminary contour based only on the input points and not a known average contour shape. However, statistical shape analysis for the purpose of calculating contours is known as is shown by Cootes in section 1, 2, 4, and the abstract. Cootes teaches in these sections the use of training sets of images with corresponding landmark points*

to create a statistical model of the object's shape and characteristics. This statistical shape model is then used for registration and segmentation by deforming the known "average contour" based on the statistical model (also referred to as an Active Shape Model). Ladak relies on discrete dynamic (deformable) contours for development of an actual contour from an initial contour, as is taught in further detail by Lobregt. Lobregt discloses in the final column of page 23 and in figure 15 that the discrete dynamic contour as used by Ladak can be successfully deformed based on any reasonably shaped initial contour. It would have been obvious to one of ordinary skill in the art to consider and use the teachings of Lobregt with Ladak since Ladak relies upon Lobregt's teachings in paragraph 0028 of his disclosure for details regarding the discrete dynamic contour. Thus, Cootes teaches the development a known "average contour" to use as an initial contour for computation of similar contours from image, and Ladak in view of Lobregt teaches the use of any reasonable initial contour. One of ordinary skill in the art at the time of the invention would have recognized that the closer the initial contour is to that of the actual contour then the less time and computations it will take to converge to the actual contour. Therefore, it would have been obvious to one of ordinary skill in the art to combine the known methods of using and calculating an initial contour based on a known "average contour" as is taught by with a noise and image artifact robust contour computational method as taught by Ladak to reduce the computational time of the process.]

and deforming the preliminary contour to fit features identified in the image to obtain the computed contour. [*Ladak teaches the deformation to fit features in paragraphs 0028 and 0061-0067.*]

Instant claim 2: A method according to claim 1, wherein the number of inputted points is fewer than the number of points needed to define the shape of the computed contour. [*Ladak teaches the number of inputted points in paragraphs 0028, 0046-0048, and Figures 1, 8-11, and 13 wherein the number of points increases or decreases with each iteration as the resolution of the curve increases or decreases depending on the complexity of the calculated contour. Inherently the complexity of the contours of real world objects requires more than the minimum number of identified points to correctly describe the contour, and thus the number of inputted points is fewer than the number of points needed to define the actual contour.*]

Instant claim 3: A method according to claim 1, wherein the number of degrees of freedom defined by the inputted points is fewer than the number of degrees of freedom needed to define the shape of the computed contour. [*Ladak teaches a 2-D and 3-D system wherein respectively the number of degrees of freedom for a point is 2 and 3 respectively. Additionally, given that (as discussed in the rejection of claim 2) the number of inputted points is fewer that the final computed contour then the number of degrees of freedom is also fewer.*]

Instant claim 4: A method according to claim 1, wherein the known average contour shape is obtained using a database of contours derived from previous images. [*Cootes in the abstract discloses that a set of training images is used to create the statistical model (average contour), and covers this in more detail in the remaining disclosure. Furthermore, it is inherent that the training images are stored in a database or other storage system since Cootes must retrieve them from some data storage unit to create the statistical model.*]

Instant claim 5: A method according to claim 1, wherein the deriving step comprises applying a parametric model to transform the known average contour shape such that the landmark points of the average contour shape match the corresponding input points. [*Ladak in paragraphs 0028-0064 discloses morphing/deforming of the contour using energy minimization parameters, force parameters, and in paragraph 0062 parameters based on the object to be contoured. Furthermore, as per rejection of instant claim 1 Ladak has taught in paragraph 0028 the transformation of the initial contour (Ladak refers to it as an outline) to a preliminary contour based on the landmark points.*]

Instant claim 6: A method according to claim 5, wherein the deforming step comprises deforming the preliminary contour by applying the same parametric model as in the deriving step. [*Ladak as per the rejection of claim 5 deforms (derives) the contours from the initial (preliminary) to the final contour. Furthermore, this deformation is done iteratively (paragraphs 0028, 0046, and 0061-0066) until a desired state is converged to.*]

Instant claim 7: A method according to claim 5, wherein the parametric model is a deformation model derived from a statistical shape model constructed from a database of contours derived from previous images. [*As per rejection of instant claim 1 the deformation of the contour is based on the initial contour which is the statistical shape model or known "average contour".*]

Instant claim 8: A method according to claim 1, wherein the contour represents the boundary of an item of interest in the image. [*Ladak teaches outlining an object of interest in figures 1 and 9-13, and paragraph 0067.*]

Instant claim 9: A method according to claim 1, wherein the image is an anatomical image. [*Ladak teaches outlining an object of interest in figures 1 and 9-13, and paragraph 0067.*]

Instant claim 15: A method according to claim 1, wherein the number of inputted points is exactly three. [*Ladak has taught the selection of points by a user, and mentions the use of 4 points in paragraph 0048, but not three. However, this is merely an example as the method is applicable for a number of points other than the 4 that was determined to work well for the described example. See paragraph 0067 of Ladak in which the method is described as usable for segmenting images of other objects. Also, see Lobregt for further detail on the point selection method relied upon by Ladak.*]

Instant claim 16: A method according to claim 1, wherein the image is an image created using a modality selected from the group consisting of ultrasound, nuclear medicine, X-ray and magnetic resonance imaging. [*Ladak in paragraphs 0006-0008, 0017, and 0028 teaches ultrasound.*]

Instant claim 20: A computer program comprising program code means for executing on a computer the method of claim 1. [*As per rejection of claim 1 the method of performing the*

contour computation was known. Furthermore, one of ordinary skill in the art understands how to implement these methods in software to be perform them on a computer system.]

Instant claim 21: A computer program product carrying the computer program of claim 21. [*As per rejection of claim 1 the method of performing the contour computation was known. Furthermore, one of ordinary skill in the art understands how to implement these methods in software to be perform them on a computer system.*]

4. Claims 10-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ladak, Lobregt, and Cootes as applied to claims 1 and 8-9 above, and further in view of McInerney ("Deformable Models in Medical Image Analysis: A Survey").

Instant claim 10: A method according to claim 9, wherein the image is an image of the heart. [*Ladak teaches the outlining of a prostate in figures 1 and 9-13, and in paragraph 0067 teaches that this method is adaptable to other organs, but does not specify the organ as a heart. (Note: McInerney presents a collection and summation of common methods of dynamic contouring various objects, and matching, measuring, tracking the contours of these objects using models, templates, a priori knowledge of the shapes through statistical analysis, and various other segmentation techniques.) However, McInerney in the 3rd full paragraph of page 10 and 11 teaches using statistical models to guide deformable contours to find, segment, and measure the heart by its contours. It would have been obvious to one of ordinary skill in the art to combine the teachings of McInerney with Ladak to use the robust contouring and segmentation method as taught by Ladak on the images of a heart. Ladak teaches a method which as stated in paragraph*

0006 is robust to noise and artifacts, and thus would have been advantageous to use with images of any organs capable of being imaged by methods known at the time of the invention.]

Instant claim 11: A method according to claim 10, wherein the image is a long-axis view of the heart. [*Ladak in view of McInerney do not teach the heart image being a long-axis view of the heart, but are not limited to any particular view as they are applicable to any view of the heart that is segmentable by the method described by Ladak. Therefore, Ladak in view of McInerney teaches the long-axis view.*]

Instant claim 12: A method according to claim 10, wherein the contour represents the endocardial boundary of the left ventricle of the heart. [*McInerney in section 3.5 teaches the contouring of the endocardial boundary of the left ventricle of the heart.*]

Instant claim 13: A method according to claim 12, further comprising the step of calculating the volume of the left ventricle. [*Ladak teaches in paragraph 0005 that the contouring is used to measure the volume of the organ, but does not specify the volume measurement of the heart's left ventricle. In view of the rejection of claims 10-12 and the disclosure of motion tracking and measurement of the left ventricle of the heart by McInerney in section 3.5 the measurement of the volume of the left ventricle based on calculated contours was known to one of ordinary skill in the art at the time of the invention. Furthermore, the use of any well known and accurate contour computing method, such as the method taught by Ladak, to create the contours for calculation of the volume would have been obvious to one of ordinary skill in the art.*]

Instant claim 14: A method according to claim 1, wherein the predetermined landmark points in the image comprise: the root of the left mitral valve leaflet, the apex of the left ventricle, and the root of the right mitral valve leaflet. [*Ladak teaches outlining an anatomical object of interest in figures 1 and 9-13, and paragraph 0067, and as per rejection of claims 10-13 the use of the heart as the object of interest was known to one of ordinary skill in the art. Also, Ladak teaches the selection of the points by the user, but does not teach the selection of points of interest. However, Examiner takes official notice that it was notoriously well known to one of ordinary skill in the art to select points of high interest for increased accuracy of the segmentation and measurement of the organ with respect to these points.*]

Instant claim 22: A method according to claim 11, wherein the contour represents the endocardial boundary of the left ventricle of the heart. [*See rejection of claim 12.*]

Instant claim 23: A method according to claim 22, further comprising the step of calculating the volume of the left ventricle. [*See rejection of claims 22 and 12-13.*]

Instant claim 17: A method of computing the motion of a contour, for a temporal sequence of images of a subject, comprising the steps of:
computing the contour for one image of the sequence according to the method of anyone of the preceding claims; [*As shown in the rejection of claims 1-16 these methods have been taught.*]

using the computed contour as a new preliminary contour for a further image in the sequence; [*McInerney teaches in paragraph 3 of pages 10 and 11 the use of a priori knowledge in the computation of a new contour. Furthermore, as per the rejection of instant claim 1 it would have been obvious to one of ordinary skill in the art to use an initial contour that is similar to that of the actual contour.*]

deforming the new preliminary contour to fit features identified in the further image to obtain the computed contour for the further image; and [*As per rejection of claims 1-9 Ladak teaches the deformation of the preliminary contour to fit features of the image and to converge upon an approximation of the actual contour.*]

repeating the using and deforming steps to obtain a computed contour for each image in the sequence. [*The sequential deformation of images to identify motion and volumetric measurements using dynamic contours was well established as is discussed by McInerney in section 3.5. Furthermore, it would have been obvious to use the contouring method as taught by Ladak and Lobregt in view Cootes to deform a series of images with a reasonable expectation of success.*]

Instant claim 18: A method according to claim 17, wherein the computed contours represent the endocardial boundary of the left ventricle of the heart, further comprising the steps of:

calculating left ventricle volumes from the computed contours; [*See rejection of claims 12-13 and 22-23.*]

using the calculated volumes to calculate at least one of the stroke volume and ejection fraction of the heart. [*See section 3.1 of McInerney wherein it teaches that measurement of the ejection fraction of the heart is a common measurement taken from heart segmentation images.*]

Conclusion

5. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Singh ("Cardiac MR image segmentation using deformable models") – left ventricle tracking via spatial and temporal measurements using deformable models.
- Bardinet ("Analyzing the Deformation of the left ventricle of the heart with a parametric deformable model") – use of a parametric model to identify and track the contour of the left ventricle.
- Pentland ("Recovery of Nonrigid Motion and Structure") – use a dynamic deformable model (related to the method used by Ladak) to and recover the left ventricle motion and make use of modal analysis.
- Suetens ("Fundamentals of Medical Imaging") – basics of active shape models.
- McInerney ("A Dynamic Finite Element Surface Model for Segmentation and Tracking in Multidimensional Medical images with Application to Cardiac 4D Image Analysis") – spatial and temporal analysis of the heart using deformable contours.
- Cootes ("Use of Active Shape Models for Locating Structures in Medical Images") - teaches statistical shape models.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan Bloom whose telephone number is 571-272-9321. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm (EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jingge Wu, can be reached on 571-272-7429. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NB

SAMIR AHMED
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